EXHIBIT C

STATE OF NEW MEXICO
COUNTY OF BERNALILLO
SECOND JUDICIAL DISTRICT

ESTHER JASSO and ARMANDO JASSO,	)	
Plaintiffs,	)	
v.	)	No. D-202-CV-2013-05744
JOHNSON & JOHNSON; ETHICON, INC.; ETHICON WOMEN'S HEALTH AND UROLOGY; GYNECARE, INC. and ONA BERNAL,	)	
Defendants.	)	

DEPOSITION OF
RUSSELL F. DUNN, PH.D., P.E.
Taken on behalf of the Defendants
November 20, 2015

RUSSELL F. DUNN, PH.D., P.E.
was called as a witness, and after having been first duly sworn, testified as follows:

EXAMINATION BY MR. DAVIS:

Q. Good morning, Dr. Dunn. Again, I'm Paul Davis, and, as you know, we just met, I think -- is that correct? -- for the first time?

A. That's correct.

Q. Okay. I'm going to bypass some of the usual introductions, because I know you've been deposed several times -- a number times by this time; is that correct?

A. That is correct.

(Whereupon Exhibit 1 was marked as an exhibit.)

BY MR. DAVIS:

Q. Okay. Let me just start by handing you what's been marked as Exhibit 1, the notice for your deposition.

And we requested production of documents.

Did you bring any documents with you today?

A. I did. I brought four notebooks of

Because products are used in different applications. You would have to test it in a similar circumstance to that application.

Q. Well, just make sure this is clear.

Do you know of any written standard adopted by the medical device industry for testing a medical device for oxidative degradation effects?

A. Well, you keep saying a "standard," and I would say that no such thing would exist. And that doesn't preclude a company from being responsible for testing for that effect.

Q. Okay. I notice in your report you talk about Ethicon's quality systems.

Do you recall that?

A. Yes, I do.

Q. And are there any written standards for quality systems for medical device manufacturers?

A. I understand that you want to use the term "standard."

There are guidelines and there are principles that are taught for quality systems. There are standards that have to do with risk analysis that would apply to medical devices, and that would affect some of the quality systems.

Q. Well --

A. What you are referring to would be something very specific that can't be applied across many different companies that are all operating in different ways.

But there are things outside of standards. There are engineering principles and there are guidelines provided. You just keep using the word "standards." And standards are not written for the quality systems, as -- as you've talked about, other than the ISO 14971 that has implications on quality.

Q. Okay. We'll get back to ISO 14971.

A. Uh-huh.

Q. I do have some questions about that.

But, aside from that written standard, do you know of any other written standards specific to the medical device manufacturing industry for quality systems, just specific to that industry?

A. I don't know that I've looked at -- specifically for a standard for quality systems for medical devices.

Q. So, when you express your opinions in this case regarding Ethicon's quality systems, what -- it sounds like you're just relying on some general principles that you go by in your

profession?

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. Let me -- let me strike that and ask it over.

Just please explain to me the standards or the guidelines that you applied in this case, the principles that you applied in this case in developing an opinion that Ethicon's quality systems were less than satisfactory.

A. Okay. The -- the -- the implication you've made is that, when we're designing or when you have quality systems, that all goes back to standards.

I teach all of the chemical engineering seniors at Vanderbilt University, and I teach a course called "Product and Process Design." It is not a course on standards. We have a full textbook of guidelines and principles. It is not built on standards. It's built on engineering fundamentals and principles that we follow in designing products and having quality systems.

And even courses that you take on quality and quality engineering are not based on standards. We teach engineering principles. And

to suggest that, if it's not in a standard, it's -- it's not scientific or it's not based on scientific principles, does not represent what standards are intended for.

Q. Okay. Have you ever heard of 21 CFR Part 820?

A. I don't know.

Q. Okay. I mean, you don't know what it is, do you?

A. Not from memory.

Q. Okay.

A. I know it's Code of Federal Regulations, and 21 represents the department that it would be associated with. I can't recall -- 19 is OSHA. I can't recall which particular division that is of the Code of Federal Regulations. I don't have that one memorized --

Q. Well --

A. -- whether I've seen it or not.

Q. I'm sorry. I apologize. I interrupted you.

Were you through?

A. Yes.

Q. Okay. Well, with respect to the Code of Federal Regulations, you mentioned OSHA.

can't tell you a specific CFR that I've looked at for FDA.

Q. Have you ever -- I apologize.

A. Go ahead.

Q. Have you ever had occasion to review any Food and Drug Administration regulations with respect to any of your work in meshes? You know, pelvic meshes or stress urinary incontinence meshes?

A. I don't recall at this time.

Q. Have you ever heard of the Medical Device Directive 93/42/EEC?

A. I'm not aware of that.

Q. Okay. Have you ever heard of ISO 13485?

A. Well, if these are specifically related to medical devices, you're asking the wrong person. I mean, Dr. Guelcher is the medical device expert that I work with.

Q. Okay.

A. But I'm not familiar with that.

Q. What --

A. He would be the one to ask.

Q. Okay. Have you ever heard of ISO 10993?

A. Yes.

Q. What is ISO 10993?

A. I don't -- I don't know off the top of my head. I know that I've heard of that -- I think I've seen that even referenced in the documents from Ethicon.

Q. Have you ever had occasion to use ISO 10993?

A. Not that I'm aware of.

Q. Have you ever had the occasion to review ISO 10993?

A. I believe I have, but unless I see the document, I don't have numbers memorized.

Q. Okay.

A. If you want to provide the standard to me, I'd be happy to look at it.

Q. Okay.

A. But I can't answer the question based on a number alone.

Q. Okay. Have you ever heard of the General Program Memorandum G-95-1?

A. Okay. If -- if you're going to keep giving numbers, I would ask that you please provide that document to me so I can see if I've seen it before.

Q. And I --

A. You're asking me if I recall a number.

Q. Okay.

A. Not as I sit here right now. But, if I saw the document, I might recall if I've seen it.

Q. Well, let me ask you this way: Have you ever read any Food and Drug Administration, you know, documents that discuss the subject of medical devices and -- and what kind of, you know, testing needs to be done on them?

A. Again, you're -- you're specifically in Dr. Guelcher's area for medical devices and biocompatibility of medical devices.

Q. With respect to a medical device, can you define the concept of harm?

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. Well, let me state it this way: With respect to a medical device, can you define the term "harm"?

MR. BOWMAN: Same objection.

THE WITNESS: "Harm" is a term that is used in the failure mode and effects analysis. It is generally related to the severity ranking that you have in a failure mode and effects analysis.

I -- I teach failure mode and effects analysis as part of the instruction at Vanderbilt University. When you define severity, every company defines it -- you're giving guidelines for what harm or severity rankings could even represent, in terms of -- is it death? Is it an injury that requires more surgery? Companies have to define that for the product that they're looking at. They have to provide a legend.

There is nothing like what you have described. There's no -- there are guidelines that are given that you can look at for how you can define harm and how you can rank harm, but every company has to come up with that and provide that themselves as they're going through the failure mode and effects analysis and as they're looking at the potential effect of -- of failure modes.

BY MR. DAVIS:

Q. It sounds like I'm hearing you say that there is no specific definition for the term "harm."

A. "Harm" is a category, and the company has to define the -- the different levels of harm. We call that severity. You -- companies actually define that.

In fact, they give a severity ranking of 1 to 10, and, next to each number, they define what that means in terms of harm. Like a 1 would be no effect, no harm. A 10 would be death, severe harm.

Do you -- you understand what I'm saying? That's how it's defined.

Q. Okay. Can you define the term "hazard" with respect to a failure modes and effects analysis for a medical device?

MR. BOWMAN: Object to form.

THE WITNESS: Let me -- (reviews documents.) I would refer you -- I understand that you -- you want a quick general statement to a very complex question.

I will refer you to ISO 14971, 2007 version. If you go to Annex D, and you find in Section D(2), "Hazards and Hazardous Situations."

The reason I can't give you a one-line definition of "hazards," you'll see that there are two pages that talk about a variety of different hazardous situations that occur with medical devices, that is specific to medical devices.

So a hazardous situation, as they've defined it, is something that could cause or lead

to harm.

If we want to find out what "harm" is, again, we can look at that standard and get some guidance on the effect that it has on a patient. And guidelines are given, but there's -- it's a lot more involved than the simple one-line definition.

BY MR. DAVIS:

Q. I noticed you just referenced ISO 14971 again.

When was the first time that you ever heard of that ISO?

MR. BOWMAN: Object to form.

THE WITNESS: I have no idea. Apparently, I purchased it -- a copy of it online January 16th of 2014.

BY MR. DAVIS:

Q. Okay.

A. That's the copy that I have printed out. I had other documents that referenced it, but I didn't have the actual standard, I believe -- I may have received a copy of it prior to that, but I actually purchased my own copy online on that date.

Q. Let's see. Your -- what exhibit number did we make your report in the TVTO case? I think you have it over there.

Exhibit 6; is that correct?

MR. BOWMAN: Object to form.

THE WITNESS: I didn't use the number ISO 14971. But I'm telling you, what I referenced was guidelines for failure mode and effects analysis, and if you want to go and get the book, you'll see it is based on ISO 14971.

BY MR. DAVIS:

Q. I've got the book.

A. Okay.

Q. I'm going to get to it.

A. Okay.

Q. But right now I just want to know, is it fair to say that you were not familiar with ISO 14971 at the time you wrote the report that's Exhibit 6?

A. That's not fair to say. I told you that that was referenced in this book.

Q. Okay. When was the first time -- let me ask you this: When was the first time you read ISO 14971?

A. The actual ISO was probably January of 2014.

Q. Okay. Have you ever had the occasion to perform a risk assessment pursuant to ISO 14971?

A. The risk assessment for ISO 14971 is specifically telling you how to perform risk analysis and failure mode and effects analysis for medical devices.

I have only performed failure mode and effects analysis hundreds of times for nonmedical devices. I teach those and require students to do failure mode and effects analysis. The technique is the same whether it's a medical device or not.

So you keep bringing it back to ISO 14971 and saying have I applied it specifically to a medical device. The answer is no.

Have I applied failure mode and effects analysis? Hundreds of times.

Q. Okay. Well, you say the standard's the same whether it's a medical device on not. So let me follow up on that.

A. No, I didn't say the standard was the same. I said failure mode and effects analysis, the technique is the same.

Q. I'll use your term. So the technique is the same. So let me follow up on that.

A. Yes.

Q. If you've got an existing device for which you've done a failure modes and effects

the body?

A. I agree that I am qualified to tell you the effects of oxidative degradation on the polymer itself and how it changes the polymer properties. And I agree that Dr. Guelcher is the expert that I work with who can tell you the effect on the body.

Q. Well, I appreciate that. But I just have a very simple question. If you'll just answer it, I'll move on.

Will you agree that you personally are not qualified to evaluate the effects or potential effects of oxidative degradation of Prolene on the body, the human body?

A. I -- I will reiterate that I can -- I am qualified to talk about the changes in the polymer properties --

Q. That's not my question. I'm sorry to interrupt you, but. . .

A. I would defer that to Dr. Guelcher.

Q. So the answer to my question? Yes?

A. No, the answer to your question is to an extent.

Q. Well -- okay.

A. I know you think it's a simple question, but, if I don't think it's a simple

understand, for instance, did you try to then go find or ask for all these documents, or not?

A. Not that I recall, because these were referenced in the FMEA, and what I was interested in was what was not included in the FMEA.

Q. Okay. Do you have any experience in developing quality systems for medical devices?

A. Well, the FMEAs -- that's a hard question for me to answer. I haven't -- I teach FMEAs, and I teach it to students who end up working in all kinds of areas. So -- I haven't applied it in a specific company, but I teach these concepts to students that go out and work for medical companies and. . .

Q. Have you ever taught about how to develop quality systems specifically for medical devices?

A. I teach generically how to do product and process design, and it's applied by chemical engineers to numerous industries. I don't teach about a specific industry.

Q. What -- what does "design controls" mean? I mean specifically for medical devices.

A. It would be parameters that you establish that you want to control those

characteristics.

Q. Okay. What -- what are the design controls generally accepted for medical devices?

A. It would be different for different medical devices.

Q. Can you -- can you just tell me what some of the design controls are for medical devices?

A. Oh. Well -- so, if I talked about the mesh component, because that's the component that I'm looking at for the medical device for the Prosima, certain design controls would be things like the weave, the diameter of the fiber, the density.

Q. That --

A. You're shaking your head no.

Q. Maybe we're on a different wavelength, because I'm asking you -- the process, the process of design controls, in designing and developing a medical device. Can you tell me what the design control processes are?

A. You're going to have to ask a -- I don't know what you're asking exactly.

Q. That's fair enough.

Do you have any experience in

maintaining a quality system for medical devices in particular?

A. It's no different for medical devices than other devices.

Q. So is the answer you don't have any specific experience for medical devices, or you do? Either you do or you don't.

A. I've never manufactured medical devices.

Q. So you've never had any experience in maintaining a quality system for medical devices; is that correct?

A. But I maintain that the quality systems I've been involved in in my work career are the same as those types of systems you'd put in place for medical devices.

Q. With that explanation, is the answer yes?

A. Ask the question again now.

Q. Have you ever had any experience in maintaining a quality system for a medical device in particular?

A. Not specifically for a medical device, but quality systems that I've maintained and been involved in in manufacturing operations are -- are

the same or very similar.

Q. Have you ever had any experience in auditing quality systems for medical devices?

A. Not specifically medical devices. Only other polymer-based products.

Q. And can you give me an overview of how you performed your audits?

A. Of other polymer products?

Q. Yes.

A. Sure. You -- you asked a question before that I guess I misinterpreted about design controls. So -- in auditing polymer-based products that I've been involved in and that we would manufacture, we had certain specifications or criteria, what I would call design controls. Certain parameters that you could measure that you were trying to target in the manufacturing process.

In -- in trying it maintain a quality system, you would go and pull random samples and test those versus your design controls.

Q. Okay.

A. If I'm understanding the question correctly.

Q. Now, do you have any experience in preparing any design controls for medical devices?

For the design and development of medical devices, that is.

A. Not specifically for medical devices; only for other polymer-based products.

Q. Okay. And what were those design controls?

A. For other polymer-based products?

Q. Yes.

A. They varied, depending on what the product was.

Q. Okay. I know it's your testimony, your opinion, that Ethicon's Prolene is subject to oxidative degradation.

I'd like to follow up on that and ask you, are there any degradation products of the oxidative degradation of Prolene?

A. Not typically. It -- the oxidative -- oxygen -- it -- it -- it depends on how it oxidizes. I need to be careful with that, because there's different oxidizing agents that can react with it. And, depending on the oxidizing agent that reacts with it, I think there can be some potential for byproducts.

In general, oxygen is attaching from some type of reactive oxygen species or even oxygen

from the air, and it breaks the chain, the long chain length of the polypropylene, into shorter chains.

Q. In that case, let's focus on Prolene in the body specifically.

A. Okay.

Q. Are there -- I know you've given the opinion that, in the body, there is oxidative degradation going on of the Prolene.

So I want to know, are there any degradation products resulting from the oxidation that -- degradation that you believe is occurring?

MR. BOWMAN: Object to form.

THE WITNESS: Can you point to in my report where I say that it's oxidizing in the body?

You said I said that it oxidized in the body. That's what -- there are reactive oxygen species in the body, but that specifically -- that oxidative mechanism inside the body is specifically what Dr. Guelcher reports on.

BY MR. DAVIS:

Q. Okay. You don't have an opinion as to whether Prolene oxidizes in the body --

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. -- is that correct?

A. No, that's not correct.

Q. Okay. Do you -- is it your opinion that Prolene, after implantation in the human body, is undergoing oxidative degradation?

MR. BOWMAN: Object to form.

THE WITNESS: Yes.

BY MR. DAVIS:

Q. Okay. And where is that in your report? I thought a minute ago you said -- you said it's not in your report.

A. It's not. I don't offer that as an opinion, and I'm not going to testify on that. But you asked if I believed that's happening. And, yes, I do believe that's happening.

Q. Okay.

A. But, the actual mechanism for how it's happening -- I say that because I've read Dr. Guelcher's report.

Q. Okay. But -- so -- my question then -- follow-up -- is, will you agree that it's not within your expertise to evaluate whether Ethicon's Prolene is undergoing oxidative degradation after implantation in the body?

A. I'm sorry. I was talking about the effect on the -- on the polypropylene itself.

Q. Well, thank you, because -- let's get back to -- let me just start over with my question, because that was not my question.

My question was do you have any expertise on the effects of oxidative degradation of Prolene on tissue in the body?

A. I do not.

Q. Thank you. Do you know what Fenton's reagent is?

A. Not off the top of my head.

Q. Have you ever heard of Fenton's reagent?

A. I don't know if I have or not. I mean, I don't recall it.

Q. Okay. I noticed in your report you -- you expressed the opinion that Ethicon's complaint handling was not satisfactory.

Do you recall that?

A. I would have to look back -- if there's a specific location -- yes.

Q. Look at the -- what? -- fourth-to-last page, the third-to-last paragraph.

A. Yes.

Not a patient and not a medical doctor.

Q. With respect to medical devices, please explain, what is "complaint handling"?

MR. BOWMAN: Object to form.

THE WITNESS: I know what it is relative to -- to polymer failure issues. And complaint handling -- because that's the background that I have. And complaint handling is getting materials back where there's been some kind of issue with -- with that particular product and running scientific tests on it to see if you can determine if there's a problem with it.

BY MR. DAVIS:

Q. Are there any written standards for -- for complaint handling with respect to medical devices?

A. I don't know that there are standards.

Q. Okay. Well -- but you say that complaint handling is part of a quality system.

Do you see that?

A. Yes.

Q. Okay. And so what's your basis for saying that complaint handling is part of a quality system?

A. My basis is working in industry, where

Q. Okay. And I notice you used the term "risk management" also.

Is that somehow different from risk assessment?

A. No. They're all related. The only thing I would tell you is risk analysis, in my opinion, gets down to the very specific tools that you employed to look at the potential hazards. So it's a subset of risk -- of risk assessment.

And when you combine risk assessment and risk analysis all together, you come up -- the overarching category is your risk management plan.

Q. Okay. Would you agree that you're not qualified to opine as to whether oxidative degradation of Prolene in the body causes any -- or has the potential to cause any harm to the body?

MR. BOWMAN: Object to form.

THE WITNESS: I can only testify to the changes in the polymer itself.

BY MR. DAVIS:

Q. Okay. So the answer would be that you do not have the expertise that I just asked about?

A. No. It would -- it would require somebody with expertise inside the body to talk about how that would ultimately affect.

Q. And you have no expertise about matters inside the body, correct?

A. To know the effect on the tissue -- I agree with what you're saying.

Q. Okay. Have you ever heard of a biocompatibility risk assessment?

A. I've -- I've heard of biocompatibility testing. I'm not sure that I've heard it combined specifically with biocompatibility risk assessment.

Q. Okay. So do you know any -- any standards, written standards that apply to biocompatibility risk assessment?

A. Only what I've read. I've not been involved in biocompatibility testing.

Q. Okay. Do you have any expertise in evaluating a biocompatibility risk assessment?

A. It -- it depends on the parameters that are being evaluated. In some cases, I could have some expertise.

Q. Well --

A. More on the chemical side. If it's a -- if there's some chemical testing that's done that I needed to look at and evaluate what that result is saying, I have expertise in that background. But I don't run biocompatibility

it has antioxidants in it.

Q. Okay. Please explain to me your scientific basis for saying that Prolene is the most easily oxidizable polymer.

A. I'm sorry. If I said it that way, I'm saying polypropylene-based resin is the most easily oxidized polymer. The only thing keeping Prolene from oxidizing as fast as polypropylene without antioxidants is the fact that it has some antioxidants in it.

Q. Okay. So let's get back to this question. You said, "Prolene oxidizes readily."

Explain what you mean by "readily."

A. That as soon as the antioxidants are expended, Prolene will oxidize easily. It's the most easily oxidized polymer, polypropylene.

Q. In the body, how long does it take for the antioxidants to be depleted from Prolene?

A. It would vary.

Q. Well, what's the shortest period of time?

MR. BOWMAN: I'm going to object to form.

BY MR. DAVIS:

Q. Or do you have the expertise to know

what the shortest period of time is?

A. I haven't studied that.

Q. Okay. Well, I understand you haven't studied it.

Do you have any expertise to evaluate the shortest period of time for Prolene to oxidize within the human body?

MR. BOWMAN: Object to the form.

BY MR. DAVIS:

Q. And when I say "oxidize," I mean use up or deplete the antioxidants.

A. I'm struggling with the "any expertise." If you gave me samples that were in the body for certain periods of times, I have the expertise to analyze them to see if they have oxidized. I don't know if that's what you're asking.

Q. That's not what I was asking.

A. Well, you said "any expertise." I do have some expertise. If you gave me the samples, I have the expertise to test them to see if they're oxidized. I thought that's what you asked, "any expertise."

Q. Now, can you tell me whether literature reviews have any role in the process of assessing

risk of degradation of Prolene in the body?

A. Certainly.

Q. What is the role of literature reviews on the process of assessing risk of degradation in the body with respect to Prolene?

A. It can help you understand whether the scientists have tested at that point.

Q. Okay. And that raises this question: In your report, you say that, if Ethicon had considered oxidative degradation, it would have done some further testing.

Do you recall that?

A. Absolutely.

Q. Tell me what that -- what the testing is that you're referring to.

A. Okay. Well, clearly, they were looking at explants, ophthalmic, vascular -- they were looking at sutures back in the '80s. And I talk about that in Section 3.2 of the report.

Q. I don't want to know what they did in the past.

I want to know what testing are you saying they should have done here, twice in your report.

A. There's -- there's a lot they could

A. I did.

Q. What animal testing, additional animal testing needed to be done? Explain what they needed to do.

MR. BOWMAN: Object to form. This is asked and answered.

MR. DAVIS: No, it's not.

THE WITNESS: I'm not going to, in two minutes, design a highly technical study. You would do it as a group and get together and talk about -- just like they did in their memos. They're -- they're getting together and talking with multiple parties.

You would get the right individuals together and -- and say, we're seeing oxidation at this point; what can we do as the next steps to further verify this is occurring?

BY MR. DAVIS:

Q. Well, you've expressed the opinion twice in your report that Ethicon needed to do further testing.

Can you sit here today and tell me any specific test, describe any specific test that you're saying Ethicon should have done?

MR. BOWMAN: Objection as asked and

answered.

BY MR. DAVIS:

Q. Please answer the question.

A. I'm telling you that they should have more explants -- they should have implanted in -- in more controlled environments and taken those explants and done much more FTIR, much more microscopy. All the things that they were doing that they stopped doing. They should have done crack evaluations. All of that would have led them to understand that this is occurring in the body.

Q. Okay. Are you basing this -- these opinions on needing further tests, are you basing them on any written standard?

A. It's not a standard that requires you to do this.

Q. It's just your opinion?

MR. BOWMAN: Object to form.

THE WITNESS: It's -- it's my opinion, based on teaching product design and a standard of care that companies have to have. You keep saying a "standard" because -- standards are very specific. I think that they had a duty as a manufacturer to do more testing based on the -- their own internal testing.

BY MR. DAVIS:

Q. I want to follow up on a subject that I talked about a few minutes ago that I omitted something.

Can you give us at least a general time frame, as best you can, about how long it takes Prolene to oxidize in the body?

MR. BOWMAN: Object to form.

THE WITNESS: I believe I said --

BY MR. DAVIS:

Q. What I mean by "oxidize" again is deplete its antioxidants.

A. I believe what I said was it's variable. As a chemical engineer, it's variable because you need the species to react with it. There's a lot of other parameters, including the stress that the material's under.

So, no, I can't give you a time frame because it would vary in different patients.

Q. Okay. Can you give me your estimate of the minimum time frame?

A. I've not tried to determine that.

Q. Okay.

A. Well, can I --

MR. BOWMAN: Just wait for a question.

MR. DAVIS: I'm sorry?

MR. BOWMAN: I said I could clear this up with deposition testimony that was taken, you know, a year ago on the issue.

MR. DAVIS: Uh-huh.

MR. BOWMAN: Would you -- I mean, I could also just tell you what happened.

MR. DAVIS: Okay.

MR. BOWMAN: It was a misprint. He didn't look at any of the exemplars for that report --

MR. DAVIS: Okay.

MR. BOWMAN: -- the TVTO report.

MR. DAVIS: Okay.

BY MR. DAVIS:

Q. And then let me just follow up.

Do you rely in this case on any exemplar meshes in forming your opinions?

A. No. It's not in my report. No.

Q. Okay. Bear with me one second.

A. Sure.

Q. In your -- let's go back again to Exhibit 6, your earlier TVTO report.

A. Got it.

Q. And on that same page, the very bottom

of that third page, you have a bullet point where you say, "Ethicon has not studied the effect of polypropylene's reactivity in vivo."

Do you see that?

A. Yes.

Q. And you took that bullet point out in your current report.

So I would like to know, why did you take that out?

MR. BOWMAN: Object to form.

THE WITNESS: Because both Dr. Guelcher and I have written reports on the Jasso matter, and he covers that in his report.

BY MR. DAVIS:

Q. Okay. What is polypropylene's reactivity in vivo? I mean, are you qualified to discuss that, or is that for Dr. Guelcher to discuss?

A. Well, I know -- I will let him discuss that. I know it involves the reactive oxygen species in the body, but that's his area of expertise.

Q. That's not your area of expertise, is it?

A. No. Just that, if the oxidizing agent

is present and if the polypropylene oxidizes, what the effect will be.

Q. In your current report on page -- on the second page, in the third paragraph, you reference the design process used by Ethicon for the Prosima device.

Do you see that?

A. Where?

Q. In the third paragraph at the top of the second page of Exhibit 2, the paragraph begins, "The focus of this report."

Do you see which paragraph I'm on?

A. Yes.

Q. And in that paragraph you reference the design process used by Ethicon for the Prosima device.

Do you see that?

A. Yes.

Q. Can you tell me what standards govern that design process?

MR. BOWMAN: Object to form as asked and answered.

THE WITNESS: No. Other -- other than I -- I'm really specifically talking about, in the design process, the design FMEA, and we've already

Q. So, again -- what I'm trying to get at, though, are you saying that you need to go back to the FMEA itself and now create a new version of it? Is that what you mean by "update"?

A. Yes. Okay. So what is typically done is you have revisions, and you can have Revision B, C, D.

So, whenever you do a revision to an FMEA, what you go -- and you look at the table, the table of the potential failure modes, all the analysis, much of which you have seen already today. And you look at any items that already exist that you need to update information on, you've learned something new about it. Or perhaps there's some new potential failure modes that you don't have a line item for that you need to add. That's updating.

Q. Okay. I understand this concept that you're expressing about -- about evaluating, you know, new risks and so forth.

But are you saying that there's a standard somewhere that required you to actually go back and put it all in a revision to the FMEA?

MR. BOWMAN: Object to form.

THE WITNESS: Yes. It's a living

document. You -- as you learn more -- any time -- a simple example was the internal studies.

And, as they felt that oxidation was occurring -- whether they -- whether they think it's really oxidizing or not, there was enough evidence in the '80s and then even later with external consultants coming in and saying Prolene will oxidize, polypropylene will oxidize.

All of this should have been fed back into the appropriate failure mode and effects analysis so that that was adequately evaluated and investigated.

BY MR. DAVIS:

Q. Okay. You've already testified that "risk management" is a much broader term than an FMEA risk analysis, right?

A. Right. But the FMEA is the tool they choose -- they chose to use to systematically look at all the risk and to analyze all the risk --

Q. Okay.

A. -- and all the potential failure modes.

So if you're telling me there's a potential failure mode that didn't end up on the FMEA, that's inappropriate. That's inaccurate. Because they chose the FMEA as their tool.

is it?

A. No, it shouldn't be. The FMEA is specifically looking at safety.

Q. Well, a risk -- a benefit/risk analysis is looking at safety, isn't it?

MR. BOWMAN: Object to form.

THE WITNESS: Not necessarily.

BY MR. DAVIS:

Q. Hmm. Okay.

A. It can look at safety as part of it. And it certainly can look at the risk associated with something that's unsafe.

Q. Okay.

A. In many cases a company will choose to do something that's unsafe because the benefit financially is worth it to them.

Q. By the way, you talk about page 6 of Exhibit 9.

I take it you'll agree that -- that -- you agree with the process depicted in the chart on page 6, right?

A. I -- I don't have a problem with this exhibit.

Q. Okay. Well, I mean, you would agree that 14971 ISO is an authoritative source to you,

right?

A. It -- it is a good source. It is updated, too, you know?

Q. Okay. And, of course, you can see on page 6 in the chart, it -- when it wants you to feed information back into the FMEA, it actually has arrows directing you to do that, right?

A. It -- it is showing that. And I looked at that previously.

Q. It doesn't show an arrow putting -- directing the postproduction information to go back into the risk analysis, does it?

A. It -- it does not. And that would be something that I would suggest that they would change in the next version. Because it says that it goes into the risk management process. And when you look at risk management, it covers the whole line. And I'm telling you, the only place it goes back is to the FMEA.

Q. Look at page 39 for a second, please, sir, of Exhibit 9.

A. Yes.

Q. Do you understand that the -- the standard for medical devices actually gives instructions on what to consider state of the art?

chemically in published literature, such as the fact that polypropylene has been known to oxidize for decades. So I agree.

Q. In fact, you -- in your own report, you -- you point out that polypropylene has been extensively studied since the 1960s, right?

A. Outside the body, yes.

Q. Okay.

Now, do you see where, at the bottom of page 3 of 6, the FDA goes on to explain that, in analyzing the need for biocompatibility testing, you should follow ISO 10993? Do you understand that?

A. Yes.

Q. And do you also --

A. Can -- I just want to point out one more time that biocompatibility and -- and chemical degradation were in different categories in the FMEA, and everything associated with biocompatibility that we're talking about was not in the category that I am discussing.

So continue on.

Q. Because you're saying that oxidative degradation is a chemical process, as opposed to -- as opposed to going to biocompatibility?

A. That is correct. While the chemical reaction can take place in the body, it is categorized as a hazard -- and I'll find it for you -- in the ISO standard for the FMEA where it's got examples of hazards and degradation is under the chemical hazard, not biocompatibility. They clearly distinguish the differences.

So now all we're talking about is biocompatibility, which is not the subject of my report.

Q. Okay. Then let's -- let's look at ISO 10993 then.

MR. BOWMAN: I'm going to have the same warning. He has no opinions related to 10993.

MR. DAVIS: That's fine. If he has none --

MR. BOWMAN: He's got a report. You can just look at the report. We've gone through almost everything except for one of the opinions in the report. And I think that's what we're going through now. So I'm guessing -- that's why I'm letting this go on, but this is. . .

(Whereupon Exhibit 16 was marked as an exhibit.)

BY MR. DAVIS:

Q. Have you ever -- are you familiar with ISO 10993 now?

MR. BOWMAN: Object to form.

THE WITNESS: I may have seen it at some point.

BY MR. DAVIS:

Q. Will you agree that it is the international standard recognized by the FDA for biological evaluation of medical devices?

MR. BOWMAN: Object to form. Beyond the scope of his report.

THE WITNESS: I don't -- I haven't looked into that. I don't know.

(Whereupon Exhibit 17 and Exhibit 18 were marked as exhibits.)

BY MR. DAVIS:

Q. Let me hand you Exhibits 17 and 18.

Do you see where Exhibit 17 is -- is a subset of ISO 10993? It's Part 9 that deals with the framework for identification and quantification of potential degradation products?

A. Yes.

Q. And is it your testimony that -- that this standard doesn't apply -- doesn't concern

chemical degradation or oxidative degradation in particular?

MR. BOWMAN: Object to form. Beyond the scope of his report. Not a biological expert. He's a chemical engineer.

MR. DAVIS: I agree.

MR. BOWMAN: Design expert.

THE WITNESS: I don't know. I haven't looked at this.

BY MR. DAVIS:

Q. Okay. And do you see in Exhibit Number 18 that it deals specifically with -- it's Part 13 of the ISO, and it deals specifically with identification and quantification of degradation products from polymeric medical devices? Do you see that?

A. Yes.

Q. And do you see that on page 3 -- look at page number 3 of this Exhibit 18. Do you see it specifically deals with oxidative degradation? Do you understand that?

MR. BOWMAN: Object to form. Beyond the scope of his report, not referenced in his report.

THE WITNESS: I see that.

lots of documents.

I don't -- if you have a specific one that you want to point out that shows me that they considered oxidative degradation, not keep talking about this biocompatibility testing, which doesn't show me in any way whatsoever that they tested for oxidation, I'd be happy to look at any document you have.

BY MR. DAVIS:

Q. Okay. Look at the last page of Exhibit 26, please, sir.

Do you see the second line number on that page listed a hazard, "Loss of Mechanical Integrity Postoperative."

Do you see that?

A. Yes, sir.

Q. And do you see what their plan is? "Clinical study design will assess this parameter." And they referenced a clinical literature search.

You certainly understand that that's an appropriate means of addressing this potential hazard, don't you?

A. If -- if the literature is applicable.

Q. Okay. So if the -- if there's -- if there is applicable literature, you agree that a --

one proper means of evaluating this potential hazard is a clinical literature search, right?

A. I don't -- I don't believe in this case that is possible, considering their own internal tests where they see degradation and they're in the best position to evaluate their own product.

Q. Sir, you haven't done a clinical literature search on the subject matter that you're talking about, have you?

A. I've -- I've looked at a lot of -- clinical research is -- is not my specialization. Clinical documents is not my specialization. While I've looked at a lot of clinical publications, that's not -- that's not my area of expertise.

Q. Okay. So you agree, then, that it would be -- it's not your area of expertise to evaluate whether or not Ethicon's clinical literature search on this subject of loss of mechanical integrity postoperative is adequate?

A. It is within my area of expertise as it relates to polymer properties and whether or not -- if they go out and look at a clinical study, I can look at the polymer testing. Because once you take the polymer out and you do the polymer testing, all of that comes back to polymer science and

A. That's a clinical study, if I'm not mistaken. And I believe that's been addressed by Dr. Guelcher.

MR. DAVIS: Let's take a break a minute, please.

(Brief recess.)

BY MR. DAVIS:

Q. Dr. Dunn, I don't know how else to do this, but there are a number of general questions that you've been asked in prior depositions that I've read, but I guess I'm going to start running through some of them.

And I'm assuming the answer is going to be the same, but I don't know that. Things could have changed since your last deposition.

A. Okay.

Q. So I'm going to ask you some of them and let's just get a feel for it, and then maybe we'll find a way to cut some of them short --

A. Okay.

Q. -- but maybe not.

A. Okay.

Q. For instance, have you ever worked with medical implant devices?

A. Over this litigation over the past two

years -- I have worked for polymer companies, and whether or not those polymers have ended up in medical devices, I don't know.

Q. Okay. Have ever had any experience in the design or manufacture of many -- of any medical devices?

A. Only insofar as developing polymers that could end up in medical devices, that -- that I can think of at this time.

Q. Okay. But -- so you've never actually designed or -- or assisted in the design and manufacture of the device -- a medical device itself, have you?

A. No. Other polymer-based devices.

Q. Let me -- so you have had experience in the design and development of some polymer-based devices of some sort, right?

A. Many. And also the failure analysis of hundreds of polymer-based devices.

Q. But were any of those devices medical devices?

A. Not that I recall at this time.

Q. Okay. Have you ever been hired as a consultant by a medical device company?

A. No.

Q. Have you ever been hired by a manufacturer related to polypropylene generally?

A. Not that I recall, but I'm not sure about that. I don't recall.

Q. Have you ever taught a course, in whole or in part, that dealt with the use of polypropylene in medical devices or its behavior in the body?

A. I would certainly say in part.

Q. I'm sorry?

A. In part, yes.

Q. What course have you taught that dealt with the use of polypropylene in medical devices?

A. Courses that I teach on product and process design.

Q. Okay. Do they deal specifically with medical devices, or is that just general design of products?

A. I have presented just the same type of information that we presented at the conferences in classes as case studies on failure of devices.

Q. Okay. But you've never taught a course that involved the use of any of the -- the standards for medical devices that we've talked about today, have you?

A. Insofar as I teach FMEAs and require students to do FMEAs and I would tell them, just like I told you before, ISO 14971, in addition to SAE standards -- there's a bunch of standards that have FMEAs. There's not one particular one I make them use.

Q. But --

A. I could have them use 14971 as easily as I could have them use the SAE standard.

Q. Has ISO 14971 been one of your course materials in a course you've taught?

A. Insofar as I teach FMEAs and FMEAs are covered by ISO 14971. That's my answer.

Q. I mean, you understand ISO 14971 is a -- is an ISO -- it's available for sale -- for sell -- it's available, right?

A. Yes, it is.

Q. So, I mean, your students are required to go buy that ISO or --

A. No.

Q. How do they -- how do they use it?

A. You're saying if I --

Q. How do they obtain it?

A. They do not obtain that ISO standard.

Q. Okay.

A. I teach material that is consistent with that ISO standard. That's the best I'm going to answer the question.

Q. Okay. So they don't actually use that document itself, the ISO 14971, correct?

A. Not specifically.

Q. Okay. Have you ever taught a course on medical devices?

A. Not specifically.

Q. Have you ever conducted a study as to how polypropylene behaves in the human body?

A. I've -- I have evaluated explant mesh. I think that has some bearing.

Q. Okay.

MR. BOWMAN: I'm sorry. Could you repeat that last question? I didn't get that at all.

MR. DAVIS: I asked has he ever conducted a study as to how polypropylene behaves in the human body.

THE WITNESS: I don't know if I'd say it's how -- what were -- what were its properties after it was removed from the human body I've studied.

human body?

A. The Atlanta presentation that I gave to you was a joint presentation by myself and a colleague.

Q. Okay. And what -- what did you have to say in that presentation about the behavior of polypropylene in the human body?

A. I don't recall.

Q. Okay. Can you tell me just generally what you know about the behavior of polypropylene in the human body?

A. I know that, if you have reactive oxygen species present, that it will oxidize. If it oxidizes, it breaks the long chain links of the polymers into shorter chain links. You form cracks. It gets brittle and hard.

Q. And you had -- you were careful to give me two ifs in that answer; is that correct?

A. I think there was one, "if you have reactive oxygen species present."

Q. Okay. Well, it will speak for itself.

A. Okay. Was there more than one "if"?

Q. I'm not going to argue about it.

A. Okay.

Q. Have you ever published an article

concerning the use of polypropylene in medical devices?

A. No.

Q. Have you ever published an article concerning medical devices in general, or any of them?

A. Not specifically, no.

Q. Okay. Have you ever published an article or given a presentation regarding quality control systems relating to a medical device manufacturing facility?

A. Not relating to a medical device manufacturer.

Q. Have you ever published an article or given a presentation regarding the postmarket surveillance of medical devices?

A. No.

Q. Am I correct that your doctoral thesis dealt with waste minimization or large-scale process design?

A. Yes. That would probably be as good a characterization as you can do.

Q. Okay.

A. Well, it also involved some polymer effects, too, if I recall.

Q. Did your doctoral thesis deal in any way with medical devices?

A. No.

Q. Did it deal with polypropylene's -- with polypropylene's behavior in the human body?

A. No.

Q. This is similar to a question I asked earlier: Have you had any work experience with the design or manufacture of a medical device?

A. I have extensive experience in both polymer manufacturing and polymer failure analysis, which is easily extended to medical devices.

Q. But have you had any experience in the design and manufacture of the device itself, the medical device itself?

A. I consider the manufacture of polymers and the failure analysis of polymer products related --

Q. Okay.

A. -- for what a chemical engineer does.

Q. Have you ever written any books or chapters in books regarding medical device manufacturing?

A. No.

Q. Do you have any work experience with

polypropylene behavior in vivo?

A. Only what I've done on mesh-related cases.

Q. Okay. And only that which you've already explained, or is there something new you need to tell me about?

A. With respect to Ethicon, yes. We've only talked about Ethicon.

Q. Okay. Well, what other work experience do you have with polypropylene behavior in vivo?

A. Other than what we've discussed today? Other mesh-related cases.

Q. Would you estimate you've been retained in more than 100 legal cases?

A. Yes, I would.

Q. And would you agree that the pelvic mesh litigation is your first time for being retained in a case involving medical devices?

A. Medical devices, but certainly not polypropylene.

Q. Okay. It is the first time you've been retained for cases dealing specifically with medical devices, correct?

A. I thought I answered it clearly, that --

Q. I want to limit it not to polypropylene, but just to medical devices specifically.

A. I'm -- I'll answer it that I have been retained -- I've never been retained to look at other medical devices that I can recall, but that does not include evaluating polypropylene.

Q. Fair enough. Have you ever published in a medical journal?

A. No.

Q. Have you ever been involved in developing a failure modes and effects analysis for a medical device?

A. I don't know.

(Reporter interruption for clarification.)

THE WITNESS: I said I don't know.

BY MR. DAVIS:

Q. Do you agree that you are not qualified to offer opinions on how polypropylene reacts inside the body?

A. I think I've clearly answered this numerous times today, that I know what happens when polypropylene oxidizes as a polymer expert, and I know what that oxidation does to the properties.

Q. Okay. Well, you haven't evaluated the clinical safety of Prolene meshes, have you?

A. I have not.

Q. Okay. Would you agree, you're not qualified to discuss the clinical effects of Prolene mesh in the body?

A. I have not -- that's not part of what I've covered in my report.

Q. Okay. Do you have any expertise in determining whether there's any clinical risk from degradation of Prolene mesh in the body?

A. I have not covered that in my report.

Q. Are you aware of any literature suggesting that there is any clinical risk from degradation of Prolene mesh in the body?

MR. BOWMAN: This was asked and answered, but. . .

THE WITNESS: I am aware of literature that talks about the degradation of polypropylene in the body.

BY MR. DAVIS:

Q. But that's not my question. I'm talking about clinical risk.

Are you aware of any literature that's suggesting that there's any clinical risk?

A. I haven't evaluated that as part of my report.

Q. Okay. By the way, your presentations that we've talked about, the two presentations, were they funded by some -- by a third party?

A. They were funded by Polymer and Chemical Technologies.

Q. Okay. Who is Polymer and Chemical Technologies?

A. That's my company.

Q. Okay.

A. They funded all of those studies.

Q. Okay. Plaintiff's counsel were not -- did not participate in that funding?

A. They did not fund the suture or the in vitro study.

Q. Okay. In the past, you were -- you were asked about some work you were planning to do in the future, and you were asked the question, "And is it being funded by counsel?"

And you answered, "It is."

Have you done any studies or planned any studies that were being funded by counsel?

A. At one time we talked about looking at some studies that would be funded by counsel. But,

A. Certain parts of chemistry, certainly, like analytical chemistry, polymer chemistry, pretty good.

Q. Okay. Okay.

Are you a materials scientist expert?

A. Only as it relates to polymers.

Q. And are you an expert in biocompatibility?

A. No.

Q. Are you an expert in the female anatomy?

A. No. I would have to say no.

Q. And I -- I'm just trying to be complete.

A. I understand.

Q. And you're not a regulatory expert of any kind, are you?

A. No.

Q. Okay. Have you got any expertise in the proper methods for cleaning explanted mesh before studying it?

A. No.

Q. Okay. And I think you've already said you have no -- no knowledge really of Ms. Jasso at all?

CERTIFICATE

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

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